



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/581,942

04/23/2007

Pradman Qasba

65426(47992)

7990

46037

7590

06/22/2009

EDWARDS ANGELL PALMER & DODGE LLP  
PO BOX 55874  
BOSTON, MA 02205

EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

06/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,942	<b>Applicant(s)</b> QASBA ET AL.	
	<b>Examiner</b> IQBAL H. CHOWDHURY	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 22, 28, 48-52 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12, 15, 22, 28, 48-52, 54-56 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

This application is a 371 of PCT/US04/040844.

Claims 1-12, 15, 22, 28, 48-52, and 54-56 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1-7, 15, 22, 28 and 48, drawn to a non-mutated catalytic domain from a galactosyltransferase I or a polypeptide comprising said catalytic domain comprising a conservative mutation at a position corresponds to position 344 of SEQ ID NO: 6 of said domain or polypeptide, which catalyzes formation of galactose- $\beta$ (1,4)-N-acetylglucosamine moiety.

Group, II claim(s) 8-12, (Why are claim 22 and 28 separate from claim 15?), drawn to a non-mutated catalytic domain from a galactosyltransferase I or a polypeptide comprising one or more mutations at positions corresponding to position 342; 344 and 228; 344 and 229; 344, 228 and 229; and 342, 344, 228 and 229 of SEQ ID NO: 6 of said domain or polypeptide, which catalyzes formation of glucose- $\beta$ (1,4)-N-acetylglucosamine moiety.

Art Unit: 1652

Group, III claim(s) 49-51, drawn to nucleic acid encoding catalytic domain of claim 1, vector and host cell.

Group, IV claim(s) 52, drawn to a method of synthesizing galactose- $\beta$ (1,4)-N-acetylglucosamine moiety using catalytic domain of claim 1.

Group, V claim(s) 54, drawn to an oligosaccharide synthesized by the method of claim 52.

Group, VI claim(s) 55-56, drawn to a method of synthesizing glucose- $\beta$ (1,4)-N-acetylglucosamine moiety using catalytic domain of claim 8.

2. The inventions listed as Groups I - VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The nucleic acid molecule encoding catalytic domain of claim 1, catalytic domain or polypeptide having no mutation or comprising a mutation at position corresponding to 342 or mutation at positions 344 and 342 of SEQ ID NO: 6, which catalyzes formation of galactose- $\beta$ (1,4)-N-acetylglucosamine moiety of Group I, and the catalytic domain from a galactosyltransferase I or a polypeptide comprising mutation at positions corresponding to 342; 344 and 228; 344 and 229; 344, 228 and 229; and 342, 344, 228 and 229 of SEQ ID NO: 6, which catalyzes formation of glucose- $\beta$ (1,4)-N-acetylglucosamine moiety of Group II are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to polypeptide of SEQ ID NO: 6. However, this shared technical feature is not a "special technical feature" as defined by

Art Unit: 1652

PCT Rule 13.2 as it does not define a contribution over the art. A galactosyltransferase protein of SEQ ID NO: 6 known in the prior art (Beta-1,4-galactosyltransferase 1, UniProt Acc. No. P08037, created 8/1/1988), which is 100% identical to SEQ ID NO: 6 of the instant application. In addition, a mutant of bovine beta1,4-galactosyltransferase-1 (met344His) is also known in the art (Boeggeman et al. Glycobiology, 13, Nov 2003, p869, see IDS). Thus, a polypeptide of SEQ ID NO: 6, by default the corresponding nucleic acid molecule and mutant having a mutation at position 344 of SEQ ID NO: 6 or any mutant derived from SEQ ID NO: 6 does not make contribution over the prior art. Thus, lacks unity of inventions.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I - VI lack unity of invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

Art Unit: 1652

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal H. Chowdhury, Patent Examiner  
Art Unit 1652

/Andrew Wang/  
Supervisory Patent Examiner, Art Unit 1656